UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al. Case No. 1:18-op-45090 (N.D. Ohio)

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al. Case No. 1:17-op-45004 (N.D. Ohio)

MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

DECLARATION OF KELLY A. MOORE IN SUPPORT OF PHARMACY DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON CAUSATION

- I, Kelly A. Moore, declare as follows:
- 1. I am a partner at the law firm of Morgan, Lewis & Bockius LLP and counsel to Defendant Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center.
- 2. I make this declaration to place before the Court certain materials relied on in Pharmacy Defendants' Motion for Summary Judgment on Causation.
- 3. Attached as **Exhibit A** is a true and correct copy of excerpts of the expert report of Craig McCann, which was submitted on behalf of the Plaintiffs in the above-captioned case.
- 4. Attached as **Exhibit B** is a true and correct copy of excerpts of the deposition of Craig McCann, which was held on May 9-10, 2019 in the above-captioned case.
- 5. Attached as **Exhibit C** is a true and correct copy of excerpts of the deposition of James Rafalski, which was held on May 13-14, 2019 in the above-captioned case.
- 6. Attached as **Exhibit D** is a true and correct copy of excerpts of the deposition of Joseph Rannazzisi, which was held on April 26, 2019 in the above-captioned case.

- 7. Attached as **Exhibit E** is a true and correct copy of excerpts of the deposition of Thomas Prevoznik, which was held on April 17, 2019 in the above-captioned case.
- 8. Attached as **Exhibit F** is a true and correct copy of excerpts of the deposition of Kyle Wright, which was held on February 28, 2019 in the above-captioned case.
- 9. Attached as **Exhibit G** is a true and correct copy of Exhibit B to Plaintiff's Response to Discovery Ruling No. 12 as Amended.
- 10. Attached as **Exhibit H** is a true and correct copy of excerpts of the expert report of David Cutler, which was submitted on behalf of the Plaintiffs in the above-captioned case.
- 11. I declare under penalty of perjury that the foregoing is true and correct. Executed this 28th day of June, 2019.

/s/ Kelly A. Moore

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Elisa P. McEnroe MORGAN, LEWIS & BOCKIUS LLP 1701 Market Street Philadelphia, PA 19103 Phone: (215) 963-5917

Phone: (215) 963-5917 Fax: (215) 963-5001

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Exhibit A

Case: 1:17-md-02804-DAP Doc #: 1885-2 Filed: 07/19/19 4 of 59. PageID #: 66369

Confidential - Subject to Protective Order

IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE NATIONAL : MDL No. 2804

PRESCRIPTION OPIATE : CASE NO. 17-MD-2804

LITIGATION : (DAP)

:

EXPERT REPORT OF CRAIG J. MCCANN, PH.D., CFA March 25, 2019

IX. Transaction Analysis

130. I implemented various approaches to identify transactions meeting specified criteria using the non-public ARCOS Data from 2006 to 2014, supplemented with Defendant transaction data where the ARCOS Data is obviously missing transactions that are included in the transactions produced by Defendants in discovery and to the extent I have Defendant transaction data for the periods before 2006 and after 2014. I calculated the results separately for each of twelve controlled substance drug codes.⁵⁴

A. Maximum Monthly, Trailing Six-month Threshold

131. Under the first approach, I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months. For example, if the number of dosage units containing hydrocodone shipped from a Distributor to a Pharmacy in February, March, April, May, June, and July were 5,000; 10,000; 7,000; 8,000; 9,000; and 9,500 respectively, a requested transaction in August would be flagged if it would cause the number of dosage units containing hydrocodone the Distributor shipped to the Pharmacy to exceed 10,000. Any reported transactions containing hydrocodone on that date and all reported transactions containing hydrocodone from that Distributor to that Pharmacy thereafter are flagged.

132. In this approach and the others implemented below I have been asked by Counsel to assume that the Distributor did not effectively investigate

⁵⁴ I do not analyze transactions in two treatment drugs: buprenorphine and methadone.



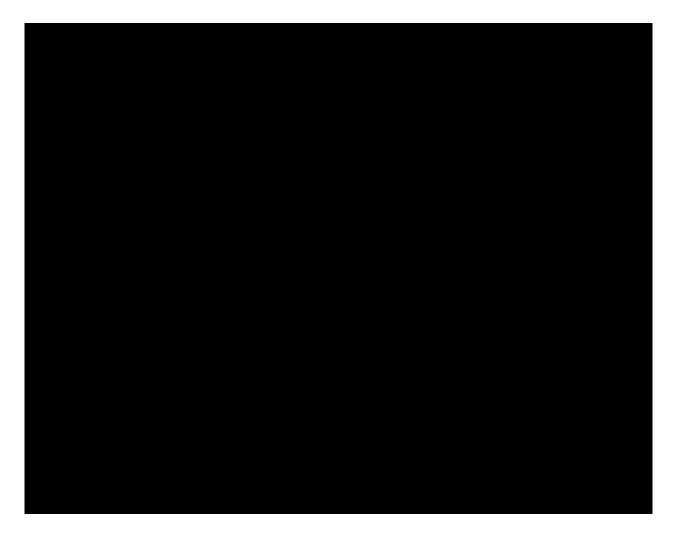
B. Twice Trailing Twelve-Month Average Pharmacy Dosage Units

136. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor. I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.



C. Three Times Trailing Twelve-Month Average Pharmacy Dosage Units

140. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor. I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.



D. Maximum 8,000 Dosage Units Monthly

- 144. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units. I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.
- 145. Figure 17 illustrates total opioid shipments into Cuyahoga County from 1996 to 2018 from ARCOS Data for 2006 to 2014 and, to the extent I have Defendant transaction data for the periods before 2006 and after



E. Maximum Daily Dosage Units

148. I identify transactions that cause the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage dosage units that varies by drug type and within some drug types by formulation.⁵⁵ I have been asked by Counsel to assume that the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction of that drug code is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.

⁵⁵ Maximum Daily Dosage Units used as specified in CAH_MDLPRIORPRO_DEA07_01384160

Exhibit B

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1
       IN THE UNITED STATES DISTRICT COURT
        FOR THE NORTHERN DISTRICT OF OHIO
 2
                 EASTERN DIVISION
 3
     IN RE: NATIONAL
                                   : HON. DAN A.
                                   : POLSTER
     PRESCRIPTION OPIATE
                                   : MDL NO. 2804
 4
     LITIGATION
 5
     This document relates to: : Case No. 17-MD-2804
 6
     The County of Summit, Ohio
     Ohio et al. v. Purdue Pharma:
     L.P., et al., Case No.
 7
     17-OP-45004
     The County of Cuyahoga v.
     Purdue Pharma Purdue Pharma
 9
     L.P., et al., Case No.
10
     18-OP-45090
11
12
             - HIGHLY CONFIDENTIAL -
    SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
13
                      VOLUME T
14
                    May 9, 2019
15
16
                  Videotaped deposition of
    CRAIG J. McCANN, Ph.D., CFA, taken
    pursuant to notice, was held at the law
17
    offices of Morgan Lewis & Bockius, LLP,
    1111 Pennsylvania Avenue, NW, Washington,
18
    D.C., beginning at 10:03 a.m., on the
19
    above date, before Michelle L. Gray, a
    Registered Professional Reporter,
20
    Certified Shorthand Reporter, Certified
    Realtime Reporter, and Notary Public.
21
22
           GOLKOW LITIGATION SERVICES
       877.370.3377 ph | 917.591.5672 fax
23
                  deps@golkow.com
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- 1 for that transaction and everything that
- 2 follows it.
- Q. Are you of the opinion that
- 4 a flagged transaction means that that
- 5 transaction represents a suspicious
- 6 order?
- 7 A. That's way beyond my report,
- 8 I think.
- 9 Q. Are you --
- 10 A. I'm sorry, I apologize. I
- don't have an opinion one way or the
- 12 other. If -- if you inferred from my
- 13 answer that I think it means that it is
- 14 not a suspicious order, I didn't mean
- 15 that. I just mean I don't have an
- opinion one way or the other.
- 17 O. Understood. But just to
- 18 make sure we are speaking the same
- 19 language. It's fair to say that you are
- 20 not taking the opinion that a flagged
- 21 transaction is necessarily a suspicious
- 22 order?
- A. Correct.
- Q. And it's also fair to say

- 1 that you are not saying that a flagged
- 2 transaction is necessarily illegal or
- 3 representative of illegal conduct?
- 4 A. Correct.
- 5 Q. It's also fair to say that a
- 6 flagged transaction in your opinion does
- 7 not necessarily mean there's been a
- 8 failure of due diligence?
- 9 A. Correct.
- 10 Q. I want to take a look real
- 11 quick specifically at this first
- 12 approach, the maximum monthly trailing
- 13 six-month threshold.
- 14 And I want to -- your --
- 15 your -- strike that.
- Your example here is very
- 17 helpful for understanding it, so I
- 18 appreciate that.
- But I want to get an
- 20 understanding for, in practical terms,
- 21 various of the defendants for different
- 22 reasons may have gaps in their data. So
- for example, they may have been serving a
- 24 pharmacy for a period of time, the

- 1 A. Section 10 doesn't deal with
- 2 individual shipments from distributors to
- pharmacies. It's at a higher, more macro
- 4 level, describing the shipments into
- 5 Ohio, and into Cuyahoga and Summit, and
- 6 how those exceed the two example
- 7 baselines that I created.
- 8 Q. Yes. And earlier you -- you
- 9 explained what the -- what you meant by
- 10 excessive shipments. And so I'm asking
- 11 you, of these excessive shipments, which
- of them should distributors have not
- 13 shipped to pharmacies?
- 14 A. I don't have an opinion one
- way or another beyond what's expressed in
- 16 Section 10 on that topic.
- Q. Were any of what you
- 18 called -- call excessive shipments
- 19 diverted?
- 20 A. I don't know.
- Q. You can't point to any of
- 22 your excessive shipments that were
- 23 diverted?
- MR. MOUGEY: Objection.

- 1 A. No.
- Q. I just wanted to make sure I
- 3 understood this very clearly. Are you in
- 4 any way relying on the opinions of, or
- 5 information from any consultants or
- 6 experts that the lawyers have retained in
- 7 this litigation for purposes of informing
- 8 your own opinions and your own report?
- 9 A. No.
- 10 Q. There were a couple of
- 11 questions earlier today about diversion.
- 12 A. Yes.
- Q. Do you remember that?
- I just wanted to make sure I
- understood, that you do not have any
- 16 opinions about the physical security that
- 17 any distributor uses or has used to
- 18 prevent diversion of controlled
- 19 substances including prescription opioid
- 20 medications, true?
- 21 A. True.
- Q. And you have not identified
- 23 any specific instances of diversion based
- on your review of any of the materials

that you've looked at in this lawsuit, 1 2 correct? A. Correct. I haven't made any 3 4 attempt to do that. One of the things that I 5 Q. understand you did, pursuant to the 6 7 lawyers' request, was to compare 8 individual defendants' transactional data 9 with the information that you saw in the DEA's ARCOS database; is that right? 10 11 Α. Yes.

Exhibit C

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1
              UNITED STATES DISTRICT COURT
           FOR THE NORTHERN DISTRICT OF OHIO
2
                   EASTERN DIVISION
3
    IN RE: NATIONAL
                                     MDL No. 2804
    PRESCRIPTION OPIATE
4
    LITIGATION
                                     Case No.
                                     1:17-MD-2804
5
                                ) Hon. Dan A.
    THIS DOCUMENT RELATES TO
6
    ALL CASES
                                    Polster
7
8
9
                   Monday, May 13, 2019
10
11
       HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12
                 CONFIDENTIALITY REVIEW
13
14
15
16
           Videotaped Deposition of JAMES E.
     RAFALSKI, held at Weitz & Luxenburg PC, 3011
17
     West Grand Avenue, Suite 2150, Detroit,
     Michigan, commencing at 9:20 a.m., on the
     above date, before Michael E. Miller, Fellow
18
     of the Academy of Professional Reporters,
19
     Registered Diplomate Reporter, Certified
     Realtime Reporter and Notary Public.
20
21
2.2
23
                GOLKOW LITIGATION SERVICES
             877.370.3377 ph | fax 917.591.5672
24
                     deps@golkow.com
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- would be expected to purchase, and I think
- that a purchase that would exceed that as a
- 3 system that would trigger that order to be of
- 4 unusual size, I don't think that's a
- 5 subjective nature.
- 6 Certainly, I quess companies
- 7 could just hire people to just look at orders
- 8 and then say that's an unusual order and that
- 9 would be more of a subjective, but I think
- any system that's designed takes the
- subjective nature out of it.
- Now, subsequent decisions may
- be subjective, but the actual identification
- would not be.
- Q. What do you mean by "subsequent
- decisions"?
- 17 A. So an order is -- triggers as
- unusual order based on the size, and then the
- company has a couple of decisions to make.
- One, and this is based on my experience and
- 21 based on the Masters case, is they could
- report it to the DEA and then not ship it and
- that could be the end of it.
- So if they want to make a
- determination on whether or not they want to

- ship it, they have to dispel the fact that
- it's a suspicious order to make sure that
- 3 it's not diverted.
- 4 So someone obviously would have
- 5 to gather some facts, and I guess make an
- 6 evaluation of those facts. So what facts
- that that person, he or she, gathers and
- 8 their opinion on whether or not it's
- 9 suspicious, I think there has to be some
- level of subjectivity in there.
- 11 You could have a checklist and
- you could have a lot of formal procedures,
- but ultimately, someone has to make some
- decision.
- 15 Q. I would ask you the same
- question about orders that deviate
- substantially from a normal pattern. Is the
- determination of whether orders deviate
- substantially from a normal pattern a
- subjective determination?
- A. My answer is kind of going to
- run parallel to the size. I think an unusual
- pattern start -- you know, first a company
- has to establish what's a usual pattern.
- In regards to the preparation

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1
              UNITED STATES DISTRICT COURT
           FOR THE NORTHERN DISTRICT OF OHIO
2
                   EASTERN DIVISION
3
    IN RE: NATIONAL
                                    MDL No. 2804
    PRESCRIPTION OPIATE
    LITIGATION
                                    Case No.
                                    1:17-MD-2804
5
    THIS DOCUMENT RELATES TO
                                    Hon. Dan A.
6
    ALL CASES
                                    Polster
7
8
9
10
                  Tuesday, May 14, 2019
11
       HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12
                 CONFIDENTIALITY REVIEW
13
14
15
16
           Videotaped Deposition of JAMES E.
     RAFALSKI, VOLUME 2, held at Weitz &
     Luxenburg PC, 3011 West Grand Avenue, Suite
17
     2150, Detroit, Michigan, commencing at
     8:25 a.m., on the above date, before
18
     Michael E. Miller, Fellow of the Academy of
     Professional Reporters, Registered Diplomate
19
     Reporter, Certified Realtime Reporter and
20
     Notary Public.
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23
24
               GOLKOW LITIGATION SERVICES
            877.370.3377 ph | fax 917.591.5672
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                     deps@golkow.com
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- 1 yesterday that you did not review any of the
- flagged orders from Dr. McCann's analysis; is
- 3 that correct?
- 4 A. I think my testimony in that
- 5 area was any specific orders. That would be
- 6 correct of what my testimony was, yes.
- 7 Q. You did not do any analysis to
- 8 see whether any specific suspicious order
- 9 caused the diversion of any specific pills
- 10 for nonmedical use, correct?
- 11 A. In regards to Dr. McCann's --
- Q. Correct.
- 13 A. That would be a correct
- 14 statement. I didn't do a specific order of a
- specific drug, if I understand your question
- properly.
- Q. Well, you asked for a
- 18 clarification of whether I was speaking about
- 19 Dr. McCann's analysis.
- You didn't do any analysis to
- see whether any specific suspicious order
- 22 caused the diversion of any specific pills,
- 23 correct?
- MR. FULLER: Object to form.
- A. I think that's an accurate

1 Sure. Yes, ma'am. Α. 2 Flagging Methodology A flagged O. 3 of all Walgreens orders by dosage unit of 4 oxycodone and hydrocodone, correct, sir? 5 Yes, ma'am. Α. 6 Is it your professional opinion 0. 7 to a reasonable degree of certainty that 8 of Walgreens orders should not have been 9 shipped? 10 Based on the conduct of 11 Walgreens and the failure to do due diligence 12 on suspicious orders, yes, ma'am. 13 Is it your opinion to a 14 reasonable degree of certainty that only 15 of orders from Walgreens stores should have 16 been shipped and available to fill 17 prescriptions for Walgreens patients? 18 Well, that would be the Α. 19 converse of this statement, but based on 20 their conduct -- I'll go back again, based on 21 their conduct and their failure to do 22 diligence after identification of suspicious 23 orders, the only conclusion I can draw is 24 that subsequent to that act, all of the 25 controlled substances were diverted.

- 1 Q. You don't have an opinion about
- whether any particular order -- you didn't
- look at any particular order to see whether
- 4 it was diverted to an illicit channel?
- 5 A. I did not --
- Q. Okay.
- 7 A. -- analyze all the orders and
- 8 try to find one or locate one that was
- 9 diverted.
- 10 Q. You didn't analyze any of the
- orders, correct, sir?
- 12 A. That's correct.
- 13 Q. You have no opinion about
- whether any particular order that was flagged
- as suspicious led to someone's addiction,
- overdose or death, correct, sir?
- A. As of today, I have no opinion
- on that matter.
- 19 Q. Do you plan on coming up with
- that opinion at some point after today?
- A. I can't rule that out if I'm
- asked to look at that or I'm provided some
- information I could review that would -- that
- would indicate that. So I can't rule out
- that that would occur.

- wouldn't have mattered in your hypothetical.
- Would you agree with me on
- 3 that?
- It's a risk of -- maybe we can
- grant you that, but if the risk never came
- 6 home to roost, then it doesn't matter, but
- you don't know that.
- A. Well, that's it. The concept
- of why we're not agreeing on this is the
- suspicious order system and the effectiveness
- of it and the due diligence is all based on
- the risk of diversion. It doesn't mean that
- diversion is going to occur. Just based on
- the serious risk, and that's what makes it a
- maintenance of effective controls requirement
- by the law.
- Q. All right. Take a look at
- page 108. So this -- I want to direct your
- attention to the top of page 108. You say:
- Mortelliti testified that while he was
- reviewing the IRR, every HCP order that
- 22 appeared on the IRR was referred out for
- 23 additional investigation which he believed
- was necessary.
- With me so far?

Exhibit D

	Page 1
1	IN THE UNITED STATES DISTRICT COURT
	FOR THE NORTHERN DISTRICT OF OHIO
2	EASTERN DIVISION
3	
4	
	IN RE: NATIONAL PRESCRIPTION MDL No. 2804
5	OPIATE LITIGATION Case No. 17-md-2804
6	
	This document relates to: Judge Dan
7	Aaron Polster
8	The County of Cuyahoga v. Purdue
	Pharma, L.P., et al.
9	Case No. 17-0P-45005
10	City of Cleveland, Ohio vs. Purdue
	Pharma, L.P., et al.
11	Case No. 18-OP-45132
12	The County of Summit, Ohio,
	et al. v. Purdue Pharma, L.P.,
13	et al.
	Case No. 18-OP-45090
14	
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17 18	Widestaned Denosition of Joseph Bernselisi
	Videotaped Deposition of Joseph Rannazzisi
19 20	Washington, D.C.
20 21	April 26, 2019 8:37 a.m.
22	0.3/ a.m.
23	
24	Reported by: Bonnie L. Russo
25	Job No. 3301876
۷ ک	00D NO. 3301070

Page 261

Q. So what is an order of unusual size?

- A. An order of unusual size is a pattern, we will say, a pharmacy that has been ordering 5,000 tablets of Hydrocodone every month for the last three years and they all of a sudden bump it up to 20,000, then 50,000, then a hundred thousand and so on. That's unusual size.
- Q. So it's unusual compared to their past practice?
 - A. Yes. One of the factors.
 - Q. What other factors?

MR. BENNETT: Objection. Scope.

THE WITNESS: They would be looking at other pharmacies that they service in that area, a pharmacy might have an unusually high purchase of a specific controlled substance in an area where everybody else was fairly consistent. That is unusual size as well.

- Q. Just a large size compared to other pharmacies in the area?
 - A. Yes.

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- Q. But that large size could perhaps be explained by nonsuspicious reasons, correct?
 - A. That's due diligence.

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Exhibit E

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1
       IN THE UNITED STATES DISTRICT COURT
        FOR THE NORTHERN DISTRICT OF OHIO
3
                EASTERN DIVISION
4
5
                            : HON. DAN A.
     IN RE: NATIONAL
     PRESCRIPTION OPIATE : POLSTER
     LITIGATION
7
     APPLIES TO ALL CASES : NO.
8
                             : 1:17-MD-2804
9
            - HIGHLY CONFIDENTIAL -
10
    SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
11
                    VOLUME I
12
13
                 April 17, 2019
14
15
                 Videotaped deposition of
16
    THOMAS PREVOZNIK, taken pursuant to
    notice, was held at the law offices of
17
    Williams & Connolly, 725 12th Street,
18
    Washington, D.C., beginning at 9:11 a.m.,
    on the above date, before Michelle L.
    Gray, a Registered Professional Reporter,
19
    Certified Shorthand Reporter, Certified
    Realtime Reporter, and Notary Public.
20
21
22
           GOLKOW LITIGATION SERVICES
       877.370.3377 ph | 917.591.5672 fax
23
                 deps@golkow.com
24
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- A. I'm not saying not at all.
- 2 But if it's -- if it's not been used
- much, and then all of the sudden it takes
- 4 off.
- ⁵ Q. Okay. And if it does take
- off, is that enough to conclude that the
- 7 product is being diverted?
- A. I don't think it's enough to
- 9 conclude that it's diverted, just based
- on that. But it should be enough to make
- it a suspicious order, to at least report
- ¹² it.
- Q. Okay. And how big an
- increase do you have in mind when you say
- 15 skyrocket?
- 16 A. I don't have a number in
- 17 mind.
- Q. It sort of depends on the
- 19 situation?
- A. It depends on the situation,
- 21 yeah.
- O. All right. How about with
- respect to unusual frequency? When a
- manufacturer receives an order from a

- THE WITNESS: Could you
- please repeat that?
- 3 BY MR. O'CONNOR:
- ⁴ Q. Not every suspicious order
- ⁵ leads to diversion, correct?
- A. Correct.
- 7 Q. I want to talk a little bit
- 8 about how suspicious order reports are --
- ⁹ are used within DEA.
- Is it fair to say that most
- 11 suspicious order reports are submitted to
- 12 field offices?
- 13 A. I would say based on the
- 14 fact that the big three are filing
- electronically, I would say the majority
- 16 electronically.
- Q. When an order or when
- 18 suspicious order reports are filed
- 19 electronically, does that mean they are
- filed with headquarters?
- A. Yes. On the Legacy and the
- vetted system.
- Q. Okay. And do registrants
- that are not reporting electronically to

Exhibit F

	Page 1
1	IN THE UNITED STATES DISTRICT COURT
2	FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION
3	
4	
5	IN RE: NATIONAL PRESCRIPTION MDL No. 2804
	OPIATE LITIGATION Case No. 17-md-2804
6	
7	This document relates to: Judge Dan
	Aaron Polster
8	
	The County of Cuyahoga v. Purdue
9	Pharma, L.P., et al.
	Case No. 17-0P-45005
10	
	City of Cleveland, Ohio vs. Purdue
11	Pharma, L.P., et al.
	Case No. 18-0P-45132
12	
	The County of Summit, Ohio,
13	et al. v. Purdue Pharma, L.P.,
	et al.
14	Case No. 18-0P-45090
15	
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17	VOLUME I
18	Videotaped Deposition of Kyle J. Wright
19	Washington, D.C.
20	February 28, 2019
21	9:33 a.m.
22	
23	
24	Reported by: Bonnie L. Russo
25	Job No. 3244302
-	

Page 212 1 Α. No. Ο. Okay. Curiosity: What is the WDO? 3 Washington district office. Α. Okay. Okay. When you said in this 4 Q. 5 e-mail that there were a large number of false 6 positives, that referred to orders that were 7 reported to suspicious but were not likely to be diverted, correct? 8 9 MR. BENNETT: Objection. Form of 10 the question. THE WITNESS: The word "diverted" 11 12 means an act that it -- my understanding of the 13 word "diverted" means an act that has already been fulfilled. It's -- it's -- it's been 14 15 taken out -- taken out of this closed system of 16 distribution. 17 MR. O'CONNOR: Okay. 18 THE WITNESS: It doesn't 19 necessarily -- source does not mean -- or 20 suspicious order does not imply that. It 21 implies that there are suspicions that need to 2.2 be resolved. Anomalies exist. 23 BY MR. O'CONNOR: 2.4 Ο. Okay. But being reported as 2.5 suspicious does not imply necessarily that it

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Page 213 will be diverted, correct? 1 Α. It does not imply that, no. 3 Earlier today we talked a little bit Ο. about -- or about ARCOS data. 4 5 At one point you were the unit chief 6 for targeting and analysis, correct? 7 Α. Correct. And that unit is responsible for 8 Ο. ARCOS data; is that fair? 9 10 It is responsible for the output 11 side of -- and making the information available 12 as needed for analytical studies, 13 investigations. But it is not responsible for 14 the input side. 15 Q. Okay. What do you mean by "the 16 output side"? 17 A. Output the product has been finalized. 18 19 Okay. Would that refer to reports Ο. 20 that are generated from ARCOS or something 21 else? 2.2 The information has gone through the 23 input side, which does several checks to make 24 sure that the data could be used and received 2.5 properly; it's been reported properly.

Exhibit G

Exhibit B (Summit County)













I. Henry Schein

Background

Henry Schein, Inc., ("Henry Schein") like the other Distributor Defendants in this case, is a registered wholesale distributor of controlled substances. However, unlike the other Distributor Defendants, Henry Schein is unique in that it is the "largest distributor of healthcare products and services to office-based practitioners in the combined North American and European markets" whose customers include "dental practices . . . physician practices, and animal health clinics." l

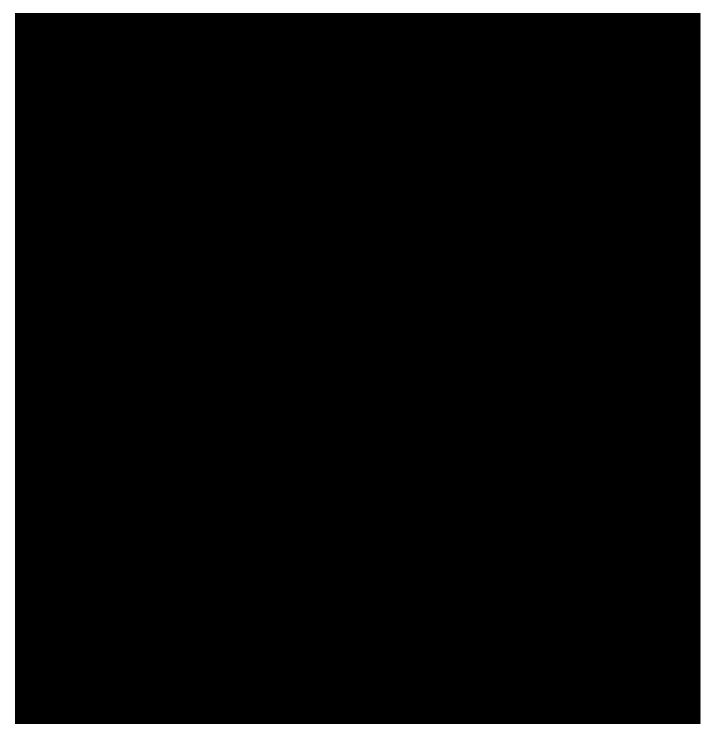
In 2015, Henry Schein reported that its sales reached a record \$10.4 billion and that it had grown at a compound annual rate of approximately 16 percent since becoming a public company in 1995. Overall, it is the world's largest provider of health care products and services to office-based dental, animal health, and medical practitioners.

II. Orders Plaintiff Summit County Contends Were Suspicious:

Plaintiff Summit County identifies the following 14 orders that Henry Schein shipped to Dr. Brian Heim ("Heim") as orders that Henry Schein knew or should have known were Suspicious Orders:



¹ See, HSI-MDL-00040712.



III. Criteria Plaintiff Used to Identify the Above Orders As Suspicious

A. <u>Henry Schein had a Duty to Identify When an Order is Likely to Be Diverted by Performing the Due Diligence Required of all Distributors.</u>

The Controlled Substances Act ("CSA") and its implementing regulations, as well as Ohio common law require distributors of controlled substances to register with the Drug Enforcement Administration ("DEA"). As registrants, distributors play a vital role in preventing diversion and therefore have a duty to perform due diligence prior to their distribution of controlled substances.

For example, pursuant to the CSA, distributors have a duty to report suspicious orders of controlled substances. An order is suspicious when it is likely to be diverted or has the potential for diversion from legitimate channels. Title 21 CFR 1301.74(b), specifically requires that a registrant "design and operate a system to disclose to the registrant suspicious orders of controlled substances." Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Moreover, "[r]egistrants that fill these orders (potential suspicious orders), without first determining that the order is not being diverted into other than legitimate medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion. Failure to maintain effective controls against diversion is inconsistent with the public interest as that term is used in 21 USC 823 and 824, and may result in the revocation of the registrant's DEA Certificate or Registration."2

In order to prevent diversion, distributors must have specific due diligence requirements and must "Know Their Customer" prior to shipping controlled substances to a particular client. In April 2011, the DEA further outlined the "Know Your Customer" requirements for distributors by expressly outlining the kinds of questions a distributor should ask customers seeking to purchase controlled substances.³ For practitioner customers – which make up the majority of Henry Schein's customer base – the DEA specifically identified the following questions:

- What is the practitioner's specialty, if any (family practice, oncology, geriatrics, pain management, etc.)?
- Do the controlled substances being ordered correspond to his specialty or the treatment he provides?
- What method of payment does the practitioner accept (cash, insurance, Medicare) and what is the ratio of each?
- Has the practitioner ever been disciplined by any state or federal authority?
- How many patients does the practitioner see each day? What is his weekly average?
- Does the practitioner prescribe as well as dispense?
- Why does the practitioner prefer to dispense as opposed to prescribe?
- Who was the practitioner's previous supplier? Are they still ordering from this supplier? If not, why are they looking for a new supplier?
- Do the hours of operation and the facility accommodate the type of practice being conducted?
- Does the practitioner's office have security guards on-site? If so, why?
- Are all applicable state, federal, local licenses current and are they issued for the registered address at which the practitioner is practicing?
- Does the practitioner see out of state patients? If so,
 - o From what states,
 - o How many,

² *Id*.

³ DEA, "Suggested Questions a Distributor should ask prior to shipping controlled substances," available at https://www.deadiversion.usdoj.gov/mtgs/pharm industry/14th pharm/levinl ques.pdf (April 2011).

- o Approximate ratio of out of state compared to local, and
- o Why, specifically, they travel so far to see him?
- Can the practitioner provide a blank copy of an agreement which they enter into with a patient, specifying the course of treatment, the patient rights and responsibilities, and reasons for termination of treatment?
- Does the practitioner conduct random unannounced drug testing?
- What measures does the practitioner employ and/or monitor to prevent addiction and diversion of controlled substances?
- Are there more than one practitioner dispensing controlled substances from the registered location?
- Do you order for just yourself or for the whole clinic?
- What controlled substances are you currently dispensing? (If only one or two controlled substances are being ordered, have the practitioner fully explain why he administers or dispenses only these specific controlled substances).
- In what dosage levels is the practitioner dispensing (2 tablets, 4 times a day, for 30 days, or 90, 120, 240 a week, month).
- Does the practitioner prescribe as well as dispense to his patients?
- Does the practitioner prescribe the same controlled substances as were dispensed to the patient?
- How many patients is the practitioner presently treating (day, week, and month)?
- B. Henry Schein Failed to Exercise Due Diligence in its Evaluation of Dr. Brian Heim as a Customer.

Notwithstanding its obligations and the DEA's express guidance, Henry Schein failed to exercise sufficient due diligence before shipping the orders noted above. To the contrary, documents produced by Henry Schein show that, prior to shipping controlled substances to Heim, Henry Schein merely confirmed that Heim's licensure was in active status and sent Heim a one-page questionnaire on August 17, 2011.⁴

C. <u>Heim's Orders Were So Suspicious that Henry Schein Knew or Should Have Known that they</u> were being Diverted

Had Henry Schein performed any of the due diligence it was required to perform by law, it would have readily identified orders placed by Brian Heim as being suspicious. For example, Henry Schein never made any inquiry about Heim's prior criminal charges or disciplinary actions. Yet, a simple verification of Heim's Ohio medical license would have shown that in 1998, Heim entered a guilty plea to twenty-four felony counts of theft of drugs and twenty-one felony counts of illegal processing of drug documents.⁵ As a result, Heim's medical license was revoked. He

⁴ See, HSI-MDL-00001198-1210. On August 23, 2012 – after it had already been providing Brian Heim with controlled substances for nearly a year – Henry Schein sent Brian Heim an additional two-page questionnaire.

⁵ Such a verification can be easily performed through https://elicense.ohio.gov/oh verifylicense.

was offered treatment in lieu of conviction. Heim's medical license was not reinstated until later with restrictions, and he was placed on probation until January of 2005.

On May 18, 2012, Heim was indicted in the Court of Common Pleas, County of Summit, Ohio, for seven counts of aggravated trafficking in drugs and one count of tampering with evidence. He was arraigned on those charges on June 6, 2012.⁶ Significantly, Henry Schein actually shipped controlled substances to Heim on at least two occasions <u>after</u> he had been indicted in Ohio state court with trafficking in drugs and tampering with evidence.⁷

In addition to failing to ask about Heim's prior disciplinary and criminal record, Henry Schein also failed to ask other fundamental questions that would have alerted Henry Schein to the likelihood of diversion. For example, Henry Schein did not ask Heim about the percentage of controlled substances that Dr. Heim's patients purchased with cash versus other methods (although it did ask the question in general). The red flags relating to Heim's purchase of controlled substances were so clear that, in as early as 2008, a patient calling Purdue Pharma referenced Heim's suspicious practices and noted his prior disciplinary record. From January 2010 through December 2011, Heim was actually listed as the 11th top prescriber of Oxycodone/APAP in the W103 – Akron, OH Territory. Despite this, Henry Schein's due diligence file for Brian Heim does not reflect a single site visit to Heim's office.

Finally, filings in the action to recover civil penalties from Heim for his violations of federal drug laws note that the volume of Heim's purchases was so suspicious that in July 2012, a DEA Diversion Investigator reviewing ARCOS data noted that Heim was "purchasing extraordinarily large amounts of hydrocodone/APAP tablets from the pharmaceutical wholesaler Henry Schein" and obtained an administrative warrant to inspect Heim's records because of this.¹⁰

Yet, even though Henry Schein suspended Heim's orders on two occasions, it never reported any of Heim's orders as suspicious to the DEA. In fact, even on the two occasions when Henry Schein held an order placed by Heim, Schein's records indicate that it nevertheless shipped an order to Heim on the following day.

In sum, given Heim's past criminal and disciplinary history, his reputation in the community, his current criminal charges, and his excessive orders of controlled substances, the orders referenced above were so suspicious that there was no amount of due diligence that Henry Schein could have performed so as to remove every basis of suspicion that Heim was engaged in diversion. The above is a clear example of Henry Schein's failure in due diligence for "onboarding" new customers.

⁶ See, United States v. Brian D. Heim, M.D., Case No 5:13-cv-210, Memorandum Opinion and Order of January 22, 2014 (District Judge Sara Lioi), at 4 ("Judge Lioi Order"); also see, May 8, 2013 Letter with Attachments to Dr. Brian Heim from the State Medical Board of Ohio, at Exhibit 1.

⁷ See, Order No. 13 (05/21/2012) and Order No. 14 (06/05/2012) identified above.

⁸ See, PPLPMDL0030005508 (April 17, 2008 email from Purdue's Nancy Crudele, Senior Manager of Medical Services, to Purdue's Joan Zooper, Corporate Counsel, summarizing a patient call regarding Dr. Brian Heim).

⁹ See, ACTAVIS0925276.

¹⁰ See, Judge Lioi Order, at 5.

Exhibit H

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Expert Report of Professor David Cutler

March 25, 2019

maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls . . . thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market." I refer to these actions collectively as "defendants' misconduct." I also refer to the adverse health, public health, public welfare and criminal justice consequences of the opioid epidemic as "harms."

- 8. An analysis of damages incurred by the Bellwether jurisdictions due to defendants' misconduct requires an evaluation of the impact of prescription opioid shipments on harms that impose costs on Bellwether jurisdictions. As part of this analysis I also review how shipments of prescription opioids ultimately resulted in harms stemming from illicit opioids. The costs imposed on the Bellwethers from these harms are addressed in the Expert Report of Prof. Thomas McGuire (the "McGuire Report").⁶ To be clear, for purposes of this report, the impact of prescription opioid shipments on harms to the Bellwethers includes all of defendants' misconduct I described above, including all defendants who used or endorsed deceptive marketing strategies and all defendants who failed to maintain effective controls over the distribution of prescription opioids.
- 9. My analysis yields annual estimates of the share of various harms imposed on selected departments in each Bellwether government ("Bellwether divisions") that is attributable to

⁵ Cuyahoga Complaint, ¶14, Summit Complaint, ¶14.

⁶ Because aspects of analyses presented in the report are related to analysis included in the Expert Report of Professor Jonathan Gruber ("Gruber Report"), the Expert Report of Professor Meredith Rosenthal ("Rosenthal Report") and the Expert Report of Professor Thomas McGuire ("McGuire Report"), the following numbering convention is adopted to identify tables, appendices and back up materials from each report: Materials related to this report are identified with the prefix III (e.g., Table III.1); materials related to the Gruber Report use the prefix I; materials related to the Rosenthal Report use the prefix II; and materials related to the McGuire report use the prefix IV.

defendants' misconduct. The analysis incorporates two alternative estimates of the share of prescription opioid shipments that are attributable to misleading marketing, which are set forth in the Expert Report of Prof. Meredith Rosenthal (the "Rosenthal Report").⁷ An alternative version of my analysis reported in Appendix III.J to this report incorporates an estimate of the share of prescription opioids that should have been identified as suspicious by distributors.⁸

10. My assignment in this report thus is to evaluate the following issues identified by counsel and to answer the following questions framed by counsel:

What was the effect of prescription opioid shipments on harms that resulted in county costs?

- 1) For each administrative division for which one or more of the Bellwether governments seeks recovery, did the increase of prescription opioid shipments since 1995 contribute to harms that result in costs faced by the relevant divisions?
- 2) What is the size of these effects? For each administrative division, calculate the percentage of harm attributable to prescription opioid shipments in each year 2006-2018 for each of the Bellwether governments.
- 3) For each administrative division for which either Bellwether government seeks recovery, what is the percentage of harm attributable to prescription opioid shipments for which defendants are responsible in each year 2006-2018 for each Bellwether government?
- 4) Provide the economic rationale for your estimates.

⁷ Prof. Rosenthal presents estimates of the share of prescription opioid shipments due to defendants' misconduct using (1) a direct shipments regression method; and (2) an indirect shipments regression method. Section VI of this report incorporates the estimates from the direct regression method. Appendix III.K presents an analysis of the percent of harms due to defendants' misconduct based on the indirect regression method.

⁸ I understand certain expert reports related to distributor misconduct are not being disclosed until April 15, 2019. Appendix III.J contains inputs that will also be set forth in reports that will be disclosed that day. As set forth above, I reserve the right to modify this analysis based on filed version of those reports.

- 11. With respect to the questions posed by counsel, I reach the following conclusions:
 - The increase in prescription opioid shipments since 1995 has contributed to harms that the relevant divisions of the Bellwether governments provide services to address;
 - 2) The percentage of harms attributable to prescription opioid shipments can be economically estimated;
 - 3) My analysis of the percentage of harms attributable to prescription opioid shipments, together with analysis of the percentage of prescription opioid shipments that are due to the defendants' misconduct reported in the Rosenthal Report, yields annual estimates of the percentage of harms due to defendants' misconduct for each Bellwether division affected by the opioid crisis;
 - 4) My analysis of the percentage of costs attributable to prescription opioid shipments is confirmed by a supplementary analysis of the direct effect of prescription opioid shipments on crime;
 - 5) My methodology for computing annual estimates of the percentage of harms due to the defendants' misconduct would not be modified if the inputs are varied, so that if different percentages are assigned to the shipments attributable to the defendants' misconduct, the methodology can still be applied in estimating damages based on the modified calculations.
- 12. In preparing this report, I and staff under my direction: analyzed data; reviewed economic literature, court filings, documents produced in this litigation, and deposition testimony. A list of materials that I have considered is attached as **Appendix III.B**. The analytical and econometric methods used in this report reflect commonly established principles and techniques used in the field of health economics. Detailed discussions of each of these methods, the mechanics of the empirical estimation, their applicability, and usage in the academic literature can be found in Sections III through V below.
- 13. Health economics is a well-recognized subfield of economics which provides an appropriate framework for analyzing the sources and impact of the opioid crisis. There are